comes were quantified using a correlational matrix to determine relationship between different endpoints.
RESULTS: Three OXY-XL randomized clinical trials and one open label safety trial and three TOL trials were identified. All reported rate of reduction of urinary incontinence episodes (R-UI). The OXY-XL trials reported rate of complete continence (CC), defined as percent of patients with no UI episodes for 7 days. Mean CC rates for OXY-XL ranged from 41% to 50% (mean CC rate = 45.9% + 0.04). OXY-XL mean R-UI ranged from 79.5% to 89.5% (mean R-UI = 84.4% + 0.04). For TOL, R-UI rates ranged from 43.2% to 44.8%, (mean R-UI = 45.7% + 0.02). Computed CC rate for TOL was 24.6%. Correlation across all studies between CC and R-UI was high ($r^2 = 0.9975$, $p < 0.0001$) and consistent; R-UI:CC ratios within trials ranged from 1.8 to 1.9 (mean = 1.85 + 0.08). Rate of reduction in UI episodes/week or day is approximately twice that of complete continence.
CONCLUSIONS: Rate of complete continence may be derived from a surrogate endpoint by taking approximately one half the rate of reduction in R-UI episodes weekly, allowing direct efficacy comparisons on multiple measures.

PKU2

IMPROVEMENTS IN CLINICAL OUTCOMES, HEALTH-RELATED QUALITY OF LIFE (HRQoL) AND SYMPTOM BOTHER FOR OVERACTIVE BLADDER PATIENTS TREATED WITH A NEW ONCE-DAILY FORMULATION OF OXYBUTYNIN

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Overactive bladder affects 17 million Americans who present with symptoms of urge urinary incontinence (UUI), urgency or urinary frequency. Providers and payers may select the most appropriate treatment using outcomes recommended by the International Continence Society (ICS): symptom quantification, patient's observations of symptoms and HRQoL.
OBJECTIVE: Using ICS-recommended outcome measures, efficacy of a newly approved once daily, controlled release formulation of oxybutynin (OXY-XL) was evaluated in an open-label 16-center trial.
METHOD: In this study 256 patients with urge/mixed urinary incontinence were treated with OXY-XL 5–30mg up to 18 weeks. Outcomes were assessed at baseline and maintenance dose week 12. Symptom quantification was based on 7-day diaries of voiding and incontinence events. Symptom bother was collected with the Urge-Urogenital Distress Inventory (U-UDI); HRQoL was collected with the disease-specific Urge-Incontinence Impact Questionnaire (U-IIQ).
RESULTS: Outcome was based on 206 patients with baseline and 12-week data. OXY-XL led to significant reductions in UUI episodes at 12 weeks versus baseline (−83%, $p < 0.001$). Percent of patients with complete continence increased from 5% to 46%, $p < 0.001$. At study end, patients perceived significantly less bother on all nine symptoms (i.e., urine leakage, frequency, urgency, nighttime urination) measured by the U-UDI (mean change = −49%, range −30 to −62%, $p < 0.001$). HRQoL was significantly improved as measured by the U-IIQ overall score (+59%, $p < 0.001$) as well as all eight domains (range +59% to +61%, $p < 0.001$).
CONCLUSION: Patients treated with OXY-XL had statistically significant improvements in all outcomes: UUI episodes, complete continence, HRQoL and symptom bother.

PKU3

LINGUISTIC VALIDATION OF THE URINARY INCONTINENCE QUALITY OF LIFE QUESTIONNAIRE

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The increasing number of quality of life (QoL) assessments in multinational clinical trials emphasizes the need for cross-culturally valid instruments to pool data across countries. The Urinary Incontinence QoL Questionnaire is a 28-item questionnaire developed in French and designed for use in women with urinary incontinence and investigates five domains and overall QoL. Prior to use in an international trial, the original questionnaire underwent linguistic validation in six countries.
METHODS: The rigorous methodology involved recruiting a QoL specialist in each country to supervise the linguistic validation process. For practical reasons, a UK English version was produced prior to the other translations as a translation basis along side the French original. The following methodology was employed: two forward translations by two native target language speakers; back-translation into French; comprehension test in a sample target population and international harmonization. The remaining languages followed the same process basing themselves both on the French and UK texts during forward and backward translations.
RESULTS: Linguistic issues emerged, among which the translation of idiomatic French expressions such as "feeling well in one's skin" or "discouraged" for which descriptive equivalents had to be found in most languages to retain the original concept. Conceptual issues arose where the French original could be interpreted in more than one way. Close collaboration with the author was necessary to correctly interpret the original concepts and orient translations towards the correct interpretation.
CONCLUSION: A rigorous methodology ensured conceptual equivalence and acceptability of the translations. Psychometric testing will be conducted to ensure reliability and validity of each translation, appropriateness of